Rapid Assessment of a Drug Quality Assurance Program and Drug Quality Control Systems

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Acknowledgements and Note from the Author

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From the Author

This assessment tool was successfully field-tested in Madagascar and in Ghana during 2003 and 2004. This document is open for further contribution and comments; please direct your feedback to the author at sxp@usp.org.

Acronyms and Abbreviations

API	Active pharmaceutical ingredient
DRA	Drug regulatory authority
GMP	Good manufacturing practices
NDQCL	National drug quality control lab
NGOs	Non-governmental organizations
QA	Quality assurance
QC	Quality control
SOP	Standard operating procedure
sqKM	Square kilometer
USD	United States dollars
USP DQI	United States Pharmacopeia Drug Quality and Information Program
WHO	World Health Organization

1. Introduction

Problems related to the quality and safety of medicines are becoming an increasing concern in many places around the world, especially in developing countries. Adequate drug legislation and regulations, competent drug regulatory authority, and appropriate drug information are required to ensure the safety, efficacy, and high quality of medicines.

Legal structures are the foundation of drug regulation. In some countries, drug laws may not cover certain aspects of pharmaceutical activity. For example, the production of certain drugs for domestic use may not require compliance to good manufacturing practices (GMP) or clinical study data may not be mandatory requirements for drug registration. Many drug regulatory agencies (DRAs) do not provide documented standard procedures for registration; others do not have written guidelines and checklists for inspection. All this has resulted, *inter alia*, in a regulatory gap and inconsistent enforcement of laws, which often leads to less clarity and more incoherence in the drug regulatory process.

All DRA functions must work in concert in order to provide effective public health protection. Key functions are licensing, product quality assessment and registration, inspection of manufacturing facilities and supply channels, laboratory control, and post-marketing surveillance for quality, adverse drug reactions, and control of drug promotion and advertisements.

Objectives of the assessment

1. To determine whether or not a functional and operational drug regulatory authority exists in the country;
2. To examine what approaches and mechanisms the country uses to ensure the quality of pharmaceuticals sold there and, if there is a drug regulatory agency, how it carries out its responsibilities;
3. To identify strengths and weaknesses of the country's drug quality assurance program and quality control systems and the reasons for them;
4. To make suggestions and, where appropriate, recommendations to policy-makers, decision-makers, and authorities responsible for designing and developing appropriate drug QA/QC systems adaptable to their political and socio-economical conditions.

2. Methodology

2.1. The methodological framework

The methodology of this assessment is based on the following framework (See Figure 1.):

- **Pre-marketing quality assessment** – includes the assessment of drug product quality, safety, and efficacy for registration or market authorization.

- **Regulatory functions** – cover central administration (allowing the functioning of a regulatory authority), quality control or testing, inspection services, licensing of persons and pharmaceutical establishments, and product recall.

- **Technical elements** – deal with norms, standards, specifications and procedures, and good practices.

- **Post-marketing surveillance** – covers monitoring for drug quality and adverse drug reactions, and control of drug promotion and advertising.

Figure 1: Assessment framework indicating key components of a drug quality assurance

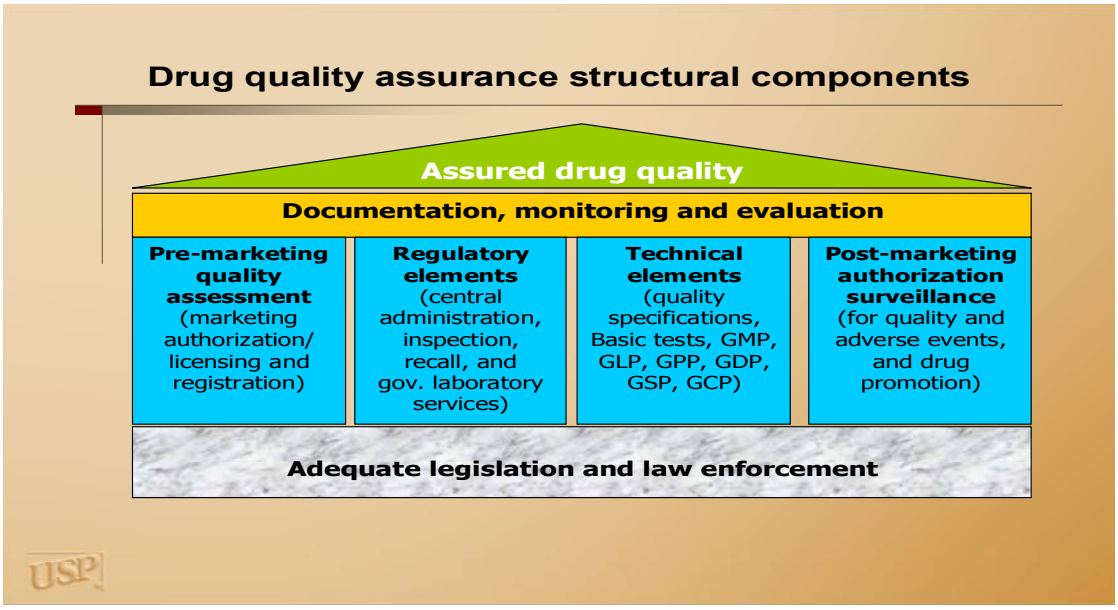
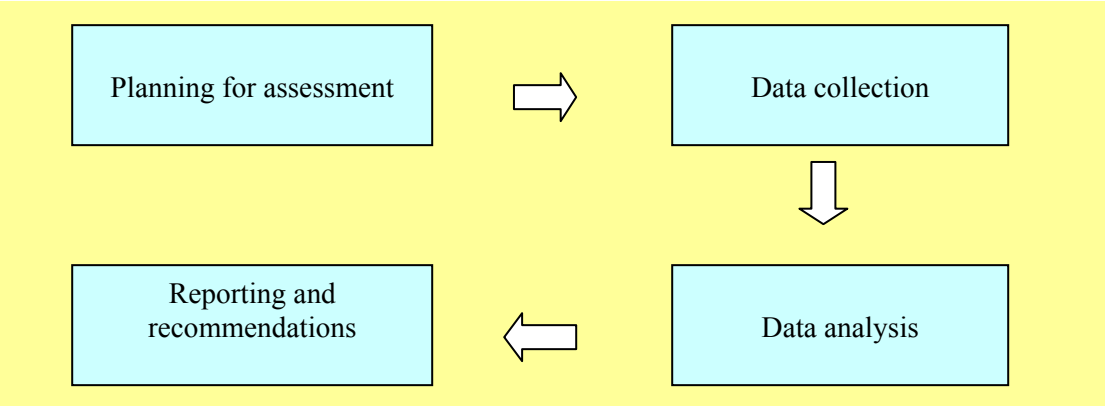


Figure 1 also illustrates the framework for data collection and the focus areas for assessment of the structural components of drug quality assurance.

2.2. The assessment process

The process to assess a drug quality assurance program and drug quality control system of a country's drug regulatory agency is illustrated below. (See Figure 2.)

Figure 2: Assessment process



2.2.1. Planning for assessment

Step 1: Set up an Assessment Team or Working Group. The planning usually starts with establishment of an independent Assessment Team or Assessment Working Group with defined role and scope of work. The Team should consist of a Team Leader and two experienced professionals in pharmaceutical technical and regulatory affairs, and in health and medicinal drug policy analysis. To reduce the potential bias in the process while ensuring transparency and avoiding potential conflict of interest, the assessment should be carried out by a non-governmental organization, e.g., an academic institution such as university or a private organization. It can also be done by an international organization.

It is essential that the assessment, including the appointment of the Team and its role and scope of work, is approved by the relevant authority. In many instances, the Ministry of Health or Drug Regulatory Authority is the responsible body to approve it. This approval should be secured before any activities of the actual assessment begin.

Step 2: Secure a financial budget based on the scope of work and timeframe described in the assessment.

Step 3: Communicate information about the assessment with all agencies, responsible authorities, and interested persons to enlist their support and cooperation. These usually include different units or divisions of the DRA (e.g., drug registration, inspection, licensing, laboratory testing, and post-marketing surveillance) and key players in pharmaceutical services, e.g., procurement agents, importers, wholesalers and/or distributors, manufacturers, and drug regulators.

2.2.2. Data collection methods and techniques

A pre-defined indicatory questionnaire will be used to guide reviewers through collection of the data and the information required for the review and assessment. (See Annex.)

Data collection will be carried out using combined techniques:

1. Conducting formal or semi-formal discussions and consultations with key officials, to include directors or deputies of chief divisions within the drug regulatory agency (DRA), government and other procurement agencies, selected key NGOs, drug testing labs, and selected key pharmaceutical establishments.

2. Studying and reviewing relevant and accessible (both published and unpublished) technical documents and records from primary and secondary sources. These include drug laws, executive orders, inspection records, DRA and National Lab annual or mid-term reports, and economic, health and drug-related indicators.

3. Using other convenient techniques, such as email, fax, and telephone.

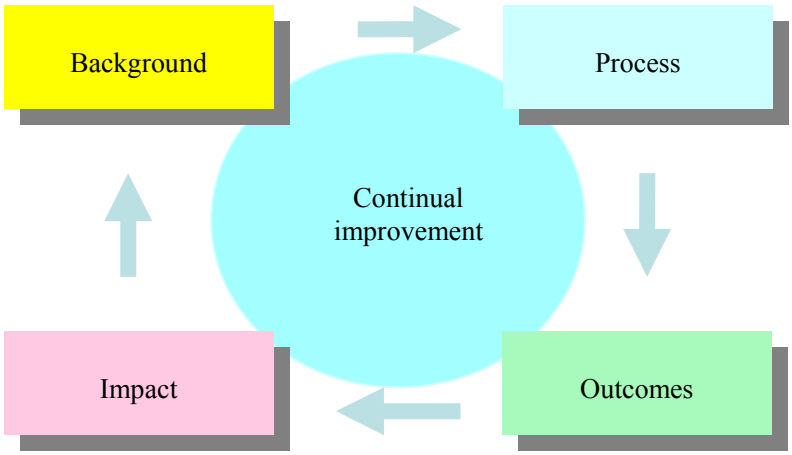
2.2.3. Method for data analysis

Quantitative data collected for each question in the questionnaire or obtained from other techniques will be examined, analyzed, and computed into percentages (if appropriate) by USP DQI experts in the field. Where necessary and appropriate, these data will be tabulated and presented in graphs for better presentation purposes.

Relationships between certain constructs of data will be identified to find possible explanations for evaluation of a drug regulatory system technical and managerial capability and, possibly, system performance.

Each relevant data set or construct representing each aspect of the country's drug quality assurance and control framework — including pre-marketing quality assessment, regulatory functions performance, technical components, and post-marketing surveillance — will be analyzed and used to explain "how" and "why" each aspect "works" or "does not work."

The analysis will be based upon the principles in Figure 3, below.



The analysis will be presented in the following structure:

- Background - General background information on demographic, economic, health, and pharmaceutical context (with key indicators on health and pharmaceutical services of both public and private sectors, drug regulatory system, drug quality assurance and control) of the country being reviewed. More specifically, data and information on drug regulatory functions and responsibilities will be added.

- Process – The mechanisms and activities by which a DRA performs. Process indicators are used to assess the effectiveness of these mechanisms and activities, particularly, legislation, regulation and enforcement of drug laws (if any); selection and registration of essential medicines; and human and financial resource allocation for various drug regulatory activities (e.g., product quality assessment, registration, inspection, testing, and continuing education).

- Outcomes – The achievement of common objectives of each country's DRA to address poor quality medicines in general and, in some cases, focus the assessment on particular disease programs, e.g., antimalarial drugs or anti-tuberculosis drugs. Outcome indicators will be used to demonstrate the degree to which these objectives are being met.

- Impact – The overall impact of the QA/QC activities on the national priority disease programs, e.g., reduction of poor quality medicines over time and an increased budget allocation by the government for QA/QC work.

- Continual improvement – The overall goal for the government (including Ministry of Health, drug regulatory authority, malaria control program, the national laboratory for drug quality control) and others to achieve.

  It is reasonable to assume that if good results are achieved from process indicators, the outcome indicators should also show positive results or improvement over time. If the outcome indicators suggest significant problems when the structural and process indictors indicate good results, however, policy-makers and regulators should investigate the problems, identify causal factors, and revise strategies accordingly.

2.2.4. Reporting and recommendations

The report of the assessment should be based on the findings of data analysis as mentioned in point 2.2.3. and should be presented in an appropriate format for easy comprehension and quick action. Main findings and appropriate actions recommended should be included in the report, as should key issues and problematic areas of the QA/QC systems to be addressed. In the recommendations, prioritization is critical of issues and problems to be addressed or areas of strengthening due to the lack of resources or budgetary constraints. Where appropriate, a proposed step-wise process should be described.

Information Collection Questionnaire

The questionnaire below serves as a guide to obtain general information and specific data for the review and assessment of a drug quality assurance program and drug quality control system. It is organized into four major categories based on the methodological framework described above.

Note: Every effort has to be made to obtain the most up-to-date data and information. If multi-year data is involved, indicate the year next to the data. The names of interviewees or informants should be kept anonymous.

1. Background information, e.g., country information and demographic, socio-economic, health, and pharmaceutical data;
2. Pre-marketing quality assessment;
3. Regulatory functions; and
4. Technical elements.

Background Information (Indicate the year the data was collected)

1. Country information
    a. Area (in sqKM):_____
    b. Administrative divisions (# of provinces, states, districts)_____
    _____

2. Demographic and socio-economic
    a. Total population: _____
    b. Population distribution (urban vs. rural)_____
    c. Life expectancy (male/female)_____
    d. Literacy rate_____
    e. Gross domestic product per capita _____ (year:_____)

3. Health and health system data
    a. Infant mortality rate (per 1000 live births) _____
    b. Maternal mortality rate (per 100,000) _____
    c. Total government health expenditure _____
    d. Total value of international aid for health sector _____
    e. Total number of health facilities both public and private (provide data in Table below) – indicate the year the data applied _____

Health Facilities	Government/Public	Private
Central		
Provincial/State		
District		
Health Center		

4. Pharmaceutical sector data - indicate the year the data applied _____
   a. Total government pharmaceutical expenditure _____
   b. Per capita drug expenditure _____
   c. Total value of domestic pharmaceutical production _____
   d. Total value of imports of finished drug products _____
   e. Total value of imports of APIs _____
   f. Total value of exports of finished drug products _____
   g. Total value of exports of APIs _____

5. Country health and pharmaceutical human resources

Description		Year
Type and number of health professional training schools		
	Medical	
	Pharmacy	
	Others, e.g., dentistry, nursing	
Number of health professionals		
	Total number of medical doctors	
	Total number of pharmacists	

6. Country pharmaceutical sector status (specify year)

No. of establishments	Government	Private	Others	Year
Pharmaceutical manufacturing plants				
For APIs				
For finished dosage forms				
For packaging finished dosage forms				
Research-based pharmaceutical industry				
Generic (incl. branded) pharmaceutical product manufacturers				
Pharmaceutical importers				
Pharmaceutical wholesalers				

7. Evolution of drug regulation
   a. The year when the drug law or regulation was first introduced _____
   b. The title of the first law/act/regulation enacted _____
      _____

c. Which of the following aspects of drug quality, safety, efficacy are covered by present drug law(s) or regulations:
- Registration – Yes_____ No_____
- Drug product licensing – Yes_____ No_____
- Pharmaceutical establishment licensing – Yes_____ No_____
- Control of drug importation – Yes_____ No_____
- Control of drug exportation – Yes_____ No_____
- Inspection services – Yes_____ No_____
- Monitoring for quality and ADR – Yes_____ No_____
- Control of drug promotion and advertising – Yes_____ No_____
- Drug quality testing/control – Yes_____ No_____
- Control of clinical trials – Yes_____ No_____
- Others (specify) – _____

d. Existence of national medicinal drug policy: Yes_____ No_____
If yes, indicate the year of its promulgation or introduction: _____
What are the main components of the policy? _____
_____
_____
_____
_____

e. Existence of national regulatory agency: Yes_____ No_____
If yes, describe its key functions:
- _____
- _____
- _____
- _____
- _____
- _____

8. Government budget allocations for drug regulatory affairs/activities: Has the government budget increased over the last three years?
Yes_____ No_____

If yes, provide figures in the following table.

Year	Government budget figure in US$
Current year:	
Last year:	
The year before	
Etc.	

If no, provide reasons, e.g., introduction of cost-recovery scheme, etc.
_____
_____

Pre-Marketing Quality Assessment and Registration

1. Existence of drug product assessment unit/team for registration
   Yes_____ No_____

2. Number of officers/professionals responsible for routine drug registration:_____
   And their professional qualifications: _____
   _____

3. Is there a specific budget for drug registration: Yes_____ No_____
   If yes, please specify sources: Government _____(year: _____)
   Fees _____(year: _____)

4. How many licenses have been issued, renewed, suspended, or revoked in the last three years?

Action	Year:	Year:	Year:
New licenses issued			
Renewed			
Suspended			
Revoked			
Other (specify)			

5. Are there unlicensed or illegal establishments engaged in the manufacture, import, export, or retail sale of pharmaceutical products in the country?

   If yes to any of the above, provide estimated number in Table below.

Type of establishment engaged in	Year:	Year:
Manufacture		
Import/export		
Wholesale		
Retail sale		

6. Does the country allow the import of unregistered pharmaceutical products?
   Yes_____ No_____

   If yes, please briefly explain under what circumstances, e.g., donated medicines or emergency: _____

7. What key professional qualifications are required to obtain a license to engage in or operate the following pharmaceutical activities?

Practice/activity	**Professional requirement**
Manufacturing	
Importing/exporting	
Wholesaling	
Retail selling/pharmacy	

8. Is GMP compliance and inspection of the manufacturing site a pre-condition for registration of a manufacturing plant?
   Yes_____ No_____

9. Key technical requirements for drug registration:
   a. Product quality, safety, and efficacy data – Yes_____ No_____
   b. Interchangeability data (e.g., BE) for generic – Yes_____ No_____
   c. Clinical trials data – Yes_____ No_____
   d. Registration in other countries – Yes_____ No_____

10. Are the same requirements applied to both innovator (branded) products as well as generics? Yes _____ No _____

    If no, what requirements are different:
    _____

11. Pharmaceutical product assessment (for registration) capability:
    a. Maximum number of pharmaceutical products assessed per year _____
    b. Number of actual pharmaceutical products assessed in
       i. Year, e.g., 2001 _____
       ii. Year, e.g., 2002 _____
       iii. Year, e.g., 2003 _____

12. Pharmaceutical product registration:
    a. Number of pharmaceutical products/preparations officially registered in the country _____ (Year_____) of which
    b. Generic (including branded generic)_____

13. Registration validation is for:
    a. 2 years _____
    b. 3 years _____
    c. 4 years _____
    d. 5 years _____
    e. > 5 years _____

14. Average fees/costs for a drug registration: _____(USD)

15. Lead time (i.e., the time span between application submission and the date of issuance of the license) taken for registering a pharmaceutical product.
    _____

16. Existence of fast-track registration system: Yes_____No_____
    If yes, indicate conditions for a product to be eligible for fast-track registration:
    _____
    _____
    _____

17. Are guidelines or instructions on drug registration available and freely accessible:
    a. On the internet or web _____
    b. In hard copies _____

18. Current registration system:
    a. Manual _____
    b. Computer-assisted _____

Regulatory Functions

(Cover central administration – allows the functioning of regulatory authority, quality control, inspection services, control of pharmaceutical promotion, advertising, and recall).

A. Central administration

1. Existence of a central administration office that oversees key pharmaceutical activities and functions (product assessment, licensing of persons, premises, and practices, registration, inspection, and post-marketing surveillance):
   Yes_____ No_____
   If yes, name it_____
   _____

2. Professional qualification and the number of people working at central administration; provide year when data/information is obtained _____

Qualification	Pharmacy/ pharmaceutical sciences	Medical Sciences	Other
Post-graduates			
Graduates			
Technicians			
Other (specify)			

3. Professional qualifications and the number of people working in the following functions; provide year when data/information is obtained _____

Function	Post-graduates	Graduates	Other (specify)
Drug product assessment			
Licensing			
Registration			
Inspection			
Post-marketing			
Other (specify)			

B. Laboratory control and testing

1. Existence of a national drug quality control lab (NDQCL)
   Yes_____ No_____
   If yes, obtain the following data and information:

2. Number and name of each unit or division of the Lab:
   Number of units/divisions: _____
   Name of each unit/division: _____
   _____
   _____
   _____
   _____
   _____

3. Professional qualification and the number of people working at NDQCL – provide year when data/information is obtained _____

Qualification	Pharmacy/ pharmaceutical sciences	Chemistry	Other
Post-graduates			
Graduates			
Technicians			
Other (specify)			

4. What kind of tests or assays the Lab can perform:
   a. Identification Yes_____ No_____
   b. Hardness (for solid form) Yes_____ No_____
   c. Loss on drying Yes_____ No_____
   d. Melting range Yes_____ No_____
   e. Residue on ignition Yes_____ No_____
   f. Disintegration Yes_____ No_____
   g. Dissolution Yes_____ No_____
   h. Assay for content of API(s) Yes_____ No_____
   i. Any of the following special tests:
      - Sterility Yes_____ No_____
      - Pyrogen Yes_____ No_____
      - Bacterial endotoxin Yes_____ No_____
      - Biovailability Yes_____ No_____
      - Bioequivalence Yes_____ No_____
      - Other (specifiy)_____

5. The Lab is capable of conducting the test for:
   a. Impurities (ordinary impurities) Yes_____ No_____
   b. Water content Yes_____ No_____
   c. Heavy metals Yes_____ No_____

6. Existence of a national pharmacopeia: Yes_____ No_____
   If yes, provide name, year first published, and current edition
   _____

7. Name of pharmacopeias officially accepted for use in the country:
   - _____
   - _____
   - _____
   - _____
   - _____
   - _____

8. Functioning lab equipment and instruments: Specify in the table below all equipment and instruments the Lab possesses and provide the information required:

Description of equipment/instrument	Model/type	Quantity	Year introduced	Functioning status
e.g., dissolution tester	Pharma Test PTZ1E	1	1996	Working - requires calibrating

9. Estimated maximum number of samples (including APIs and finished products) the Lab is able to test per year _____

10. Tests (with results) that were performed by the Lab in the current and last three years:

Total No. samples tested	No. passed quality testing	No. failed quality testing
APIs		
Year:		
Year:		
Year:		
Year:		
Finished drug products		

Year:		
Year:		
Year:		
Year:		

11. Specify the most common drug groups (e.g., antibiotic, antipyretic, anti-inflammatory, etc.) that the Lab has tested.
    - _____
    - _____
    - _____
    - _____
    - _____

12. Sites that have sent drug samples or APIs and requests for tests:
    - e.g., inspection unit of Department of Food and Drugs
    - _____
    - _____
    - _____
    - _____

13. Purposes for quality testing of drug samples in the last two years:

Purpose	No. and year:	No. and year:
Registration		
Quality monitoring		
Manufacturing (in process control)		
Request from drug industry		
Request from individuals		
Administrative or regulatory action		
Other (specify)		

14. Does the Lab charge fees for testing services? Yes_____ No_____
    If yes, indicate the average charge per sample testing _____ USD

15. Total annual budget for the Lab operation including salaries of staff
    _____ USD (year_____)

16. Total annual budget for the Lab equipment/instrument maintenance
    _____ USD (year_____)

17. Major sources of budget for the Lab operations/activities, specify:
    _____
    _____

18. Has the Lab received any technical, financial, or in-kind support from any international agencies since its establishment?

If yes, indicate estimated value or type of equipment and year of support:

- _____ year_____
- _____ year_____
- _____ year_____
- _____ year_____
- _____ year_____

19. Main constraints faced in conducting the various tests/assays in the Lab.
Circle all answers that apply:
    a. Financial constraints – low government budget
    b. Limited numbers of qualified professionals
    c. Lack of continuing education/training
    d. Limited number of adequate lab equipment/instrument
    e. Unavailability of certain reference standards/substances
    f. Unavailability of pharmacopeial specifications
    g. Unavailability of certain reagents, solvents, and indicators
    h. Other (specify) _____
    _____

20. Lab management with regard to Good Laboratory Practices.
Circle all answers that apply:
    a. Existence and use of sample receiving/collection notebook
    b. Existence and use of laboratory notebook
    c. Existence and use of analytical work book or work sheet
    d. Existence and use of lab equipment log book
    e. Existence (in written document) of safety rules and measures applied
    f. Existence and use of appropriate lab clothes, gloves, goggles, etc.
    g. Existence and use of appropriate and separate storage room for reference substances, toxic and poisonous materials, and inflammable chemicals.
    h. Working reagents, references, solutions, solvents, and samples are appropriately labeled (at least their name, concentration, date of preparation, initial of preparator, count, as necessary)
    i. Existence and use of standard operating procedures for testing
    j. Existence and use of air-sucking chamber
    k. Other _____

21. Has the Lab participated in any international or regional assessment for professional and technical competency? If yes, describe the event and the year:
_____
_____

22. Has the Lab ever been requested to test a certain product's quality by an international agency or neighboring countries? If yes, describe the event and the year:
_____
_____

23. Has the Lab received any complaints regarding its testing results in the past three years? If yes, briefly describe the event: _____
_____

C. Inspection services

1. Existence of provisions in the drug law/regulations defining the powers and status of GMP inspectors: Yes _____ No _____

2. Existence of a GMP inspectorate: Yes _____No _____
If yes, provide number of inspectors and indicate whether they also serve as inspectors for drug supply chain: Yes _____No _____

   If no, indicate whether inspection services are subcontracted:
   Yes _____ No _____

3. Relationship of GMP inspectorate to the unit/division in charge of licensing of manufacturers and product registration unit/division:
_____
_____

4. Existence of national GMP guidelines: Yes_____ No_____
If yes, give its name and year of introduction _____
_____ (year_____)
If no, what GMP guidelines are officially accepted for use in the country?
_____

5. Existence of manuals or standard operating procedures (SOPs) for GMP inspectors:
Yes_____ No_____
If yes, provide name and date of publication: _____
_____(year_____)

6. Status of application of GMP guidelines/standards for manufacturing plants:
Voluntary _____ Compulsory (required by law) _____

7. Information on current GMP inspection-related activities:

No. of plants and type of inspection	Year:	Year:	Year:
Total No. of manufacturing plants in the country			
No. of plants inspected and compliant to GMP			
No. of plants inspected for renewal of license			
No. of plants inspected because of complaints			
No. of plants inspected as follow-up			
Other (specify)			

8. Number of administrative or regulatory measures taken against GMP non-compliant manufacturing plants in the last three years:

Measures taken:	Year:	Year:	Year:
Written notice of warning			
Fines			
License suspended			
License revoked			
Production suspended			
Other (specify)			

9. Plan to increase number of manufacturing plants to comply with GMP standards:
   Yes _____ No _____
   If yes, indicate target number by year:

Target to increase GMP compliance:	Current year:	Year:	Year:
No. of GMP noncompliant manufacturing plants			
No. of GMP compliant plants			

10. Inspections in the drug supply/distribution chain – existence of inspection services in the drug supply chain: Yes _____No _____
    If yes, indicate number of inspections per year planned: _____

11. Are samples collected during inspections? Yes _____ No _____
    If yes, provide information below:

Samples collected and tested in connection with:	No. of samples collected		Passed quality testing		Failed quality testing	
	Year:		Year:		Year:	
GMP inspection						
Supply chain inspection						
Other (specify)						
Total						

12. Number of administrative and/or regulatory measures taken against practices related to producing and/or selling poor quality products in the last three years:

Measures taken:	Year:	Year:	Year:
Written notice of warning to manufacturer, wholesaler, and retailer			
Fines			
License suspended			
License revoked			
Product recall			
Product withdrawal			
Other (specify)			

13. Does the inspectorate charge fees for inspection services?
    Yes _____ No _____
    If yes, indicate rough fees charge per inspection: _____ USD

14. Existence of mechanism or system for monitoring of quality of medicines as post-marketing surveillance activity: Yes _____ No _____
    If yes, briefly describe the mechanism _____
    _____
    _____
    _____

15. Existence of product quality and adverse drug reactions reporting mechanism or system:
    Yes _____ No _____
    If yes, briefly describe the mechanism _____
    _____
    _____
    _____

16. Existence of product recall mechanism or system: Yes _____ No _____
    If yes, briefly describe the mechanism _____
    _____
    _____
    _____
    _____

17. Main constraints faced in carrying out inspection services.
    Circle all answers that apply:
    a. Financial constraints – low government budget
    b. Limited numbers of qualified inspectors
    c. Lack of continuing education/training
    d. Lack of SOP or guidelines
    e. Limited access to relevant information on inspection
    f. Other (specify) _____
    _____

D. Licensing of persons and/or pharmaceutical establishments

1. Existence of unit/team in charge of issuing, variation, suspension, and revocation of license for persons or pharmaceutical establishments. Yes_____ No_____

2. Number of officers/professionals responsible for routine licensing:_____
   Their professional qualifications: _____
   _____

3. Existence of standard operating procedures (SOPs) for licensing of persons or pharmaceutical establishments: Yes_____ No_____
   If yes, ask him/her to provide name and date of publication: _____

4. What are the main requirements and qualifications to be met for license approval of a retail pharmacy?

   □ specified location □ professional qualification – e.g., pharmacist
   □ specified list of medicines □ completion of pharmacy training program
   □ other(s)_____

5. What are the main requirements and qualifications to be met for license approval of a pharmaceutical wholesaler or distributor?
   □ specified location
   □ professional qualification – e.g., pharmacist as technical manager
   □ adequate facility with proper air ventilation and air conditioning
   □ appropriate storage areas (cold, cool, and room temperature rooms)
   □ at least 80% of the transport means are in good working conditions
   □ other(s)_____

6. How many licenses have been issued, renewed, suspended, or revoked in the last three years?

Action	Year:	Year:	Year:
New licenses issued			
Renewed			
Suspended			
Revoked			
Other (specify)			

7. Are there unlicensed or illegal establishments engaged in the manufacture, import, export, or retail sale of pharmaceutical products in the country?

   If yes to any of the above, provide estimated number in Table below.

Type of establishment engaged in	Year:	Year:
Manufacture		
Import/export		
Wholesale		
Retail sale		

E. Other relevant questions – pose to key stakeholders, e.g., drug outlets, distributors/importers/wholesalers, and manufacturers during the visit to their premises. the data collection team should be accompanied by the relevant authority (e.g., drug regulatory agency personnel) to visit the premises.

1. Retail drug outlets or pharmacies

a. Is the premise operating under a valid license, i.e., has it been licensed by the relevant drug authority and is the license still valid?
□ Yes □ No

b. Is the outlet attendant the person who holds the license?
□ Yes □ No

c. What are main sources of the medicines sold in the outlet?
Check all that apply:
□ direct from local manufacturing companies
□ from main domestic wholesaler(s)
□ other sources_____

d. Has the outlet kept all documents or papers, such as invoices, that can be used to trace the sources of medicines purchased?
□ Yes □ No

e. Any expired-date products found on the premise?
□ Yes □ No

f. Does the outlet have a refrigerator to store medicines requiring cold temperature?
□ Yes □ No

g. Have medicines been kept out of direct sunlight?
□ Yes □ No

h. Has your premise been inspected by the Inspector(s) from DRA?
□ Yes □ No

If yes, provide the number of occasions inspected by year:

Number of inspections	Purpose of inspection	Year

2. Wholesaler/distributor

a. Is the company operating under a valid license, i.e., has it been licensed by the relevant drug authority and is the license still valid?
□ Yes □ No

b. What are the main sources or suppliers of the medicines sold by the wholesaler?
Check all that apply:
□ direct from local manufacturing companies
□ direct from foreign manufacturers
□ from foreign or international distributors/suppliers
□ other sources_____

c. Have the sources or suppliers of medicines pre-qualified?
□ Yes □ No

If yes, by whom?
□ national DRA
□ international agency, please name it _____

d. Was pre- or post-shipment inspection carried out by the company before accepting any consignment?
□ Yes □ No

If yes, by whom?
□ QA/QC personnel of the company
□ national DRA official
□ sub-contracting private entity

e. Has the company kept all documents or papers, such as invoices, which can be used to trace the sources of medicines purchased?
□ Yes □ No

f. Does the premise storage facility have cold and cool rooms?
□ Yes □ No

g. Does the storage facility have the following critical components?
Check all that apply:
□ incoming medicines receiving area
□ quarantine area or room
□ (basic) laboratory testing facilities or room
□ SOPs for receiving and storing medicines
□ inventory control system (manual _____; computerized:_____)

h. Any expired-date products found in the premise?
□ Yes □ No

i. Does the premise have appropriate air ventilation and air conditioning?
□ Yes □ No

j. Has your premise been inspected by the Inspector(s) from DRA?
□ Yes □ No

If yes, provide the number of occasions inspected by year:

Number of inspections	Purpose of inspection	Year

k. What is your opinion of the current system of drug registration in terms of process (transparency, effectiveness), application time, availability of clear instructions, and fees:

_____
_____
_____
_____

Technical Elements (have been incorporated into #1-3)